UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION))))
THIS DOCUMENT RELATES TO:) Dkt. No 1:13-md-2419 (RWZ))
Suits Naming the Tennessee Clinic Defendants)))

NOTICE OF SERVICE OF DISCOVERY

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") give notice to the Court and to all parties that they have served written discovery on the following parties:

- ➤ UniFirst
- > Alaunus Pharmaceuticals, LLC
- > Ameridose, LLC
- > ARL BioPharma Inc.
- ➤ Liberty Industries, Inc.
- > Medical Sales Management, Inc.
- > Victory HVAC.

The Tennessee Clinic Defendants attach as a collective exhibit to this Notice this written discovery so as to ensure that all parties in the MDL are served with a copy. In order to most efficiently serve this discovery, paper copies (or email copies, where counsel agreed to accept service by email) have been served on the recipients of the discovery and all other parties are hereby served electronically with the discovery via ECF service of this Notice and its attachment.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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Attorneys for the Tennessee Clinic Defendants

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 20th day of March, 2015.

/s/ Chris J. Tardio

Chris J. Tardio

^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

EXHIBIT

Discovery Referenced in Notice

DISCOVERY TO UNIFIRST

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

)) MDL No. 2419) Dkt. No. 1:13-md-2419-RWZ)
))
)))

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES AND REQUESTS FOR PRODUCTON OF DOCUMENTS AND REQUESTS FOR ADMISSION PROPOUNDED TO UNIFIRST CORPORATION

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to UniFirst Corporation d/b/a UniClean Cleanroom Services ("UniFirst").

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

- 1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.
- 2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.
- 3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.
- 4. "You" and "your" refers to UniFirst and each of its present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on its behalf.
- 5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and the copy of the document;
- D. State in as much detail as possible the contents of the documents; and
- E. State the manner and date of disposition of the document.

If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and a copy of the document;
- D. State the subject matter of the document; and
- E. State the basis upon which you contend you are entitled to withhold the document from production.
- All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.
- 3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

- 4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."
- 5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.
- 6. The singular should be construed to include the plural, and the plural should be construed to include the singular.
- 7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.
- 8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On February 23, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to UniFirst Corporation.* In order to minimize the impact of discovery on UniFirst, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-5** from the *Saint Thomas Entities' First Set of Interrogatories.* The "new" interrogatories begin at Number 6.

1-5. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-5 from the Saint Thomas Entities' First Set of Interrogatories.]

ANSWER:

INTERROGATORIES

- 6. Identify by name, job title, address, phone number, and present employer (if known) all UniFirst's officers, agents, employees, representatives, and contractors who:
 - a. Performed any cleaning services at NECC's facility in 2011 or 2012;
 - b. Acted as an account manager for NECC or were otherwise designated to manage NECC's relationship with UniFirst at any point in time.

For each person identified, please state (1) when they were employed by UniFirst (if employed) and (2) when they performed cleaning services or acted as account manager for NECC's account.

ANSWER:

7. Identify and describe (1) when UniFirst began providing cleaning services to the NECC facility; (2) whether there were any breaks in the period of time that UniFirst provided cleaning services (and, if so, when and why); (3) the scope of UniFirst's work for NECC (e.g., to clean the entire facility; to clean just certain rooms; to only perform certain cleaning tasks; etc.); (4) the frequency with which UniFirst performed these services (e.g., once monthly; once weekly; daily; etc.); and (5) the nature of the services (i.e., what cleaning services UniFirst provided).

8. What dates were you at NECC's facility in 2011 and 2012 performing cleaning services? For each date, please describe the cleaning services that you provided and identify the supervisor (or person in charge) on the premises at each visit.

ANSWER:

9. Did NECC ever lodge any complaints or concerns about the quality of the cleaning services provided by UniFirst or the sterility or contamination of NECC's facilities? If so, please identify the date of the complaint or concern, describe how it was conveyed (including identifying any documents reflecting the complaint or concern), identify who conveyed it to whom, describe the substance of the complaint or concern, and describe how UniFirst addressed it.

ANSWER:

10. Identify and describe any communication prior to September 18, 2012, between UniFirst and NECC about any of NECC's products being contaminated or lacking sterility, or potentially contaminated or lacking sterility, including but not limited to methylprednisolone acetate.

ANSWER:

11. Did UniFirst perform any quality control to test the quality of its cleaning of NECC's facility? If so, please describe it, identify the date(s) that the testing occurred, and describe the results.

ANSWER:

12. Identify any contracts or agreements between UniFirst and any entities other than NECC owned in whole or in part by Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro. If any such contract or agreement exists, describe the services UniFirst provided under the contract or agreement.

13. Were any disciplinary actions taken against any employee responsible for cleaning at NECC related to their job performance? If so, please identify the employee, the date of the action, the reason for the action, and the action.

ANSWER:

14. Has UniFirst every conducted any internal investigation or audit related to NECC or the fungal meningitis outbreak? If so, please identify the date of the investigation or audit, the individuals involved in the investigation or audit, the reason for the investigation or audit, and any action taken as a result of the investigation or audit.

ANSWER:

15. Who is the UniFirst employee (or agent) or former employee (or agent) most knowledgeable about UniFirst's relationship with NECC and its cleaning of NECC? Please identify the person by name, job title, employer, and contact information.

STATE OF ________)

COUNTY OF)		
I,, after being duly so		
Sworn to and subscribed before me this	_ day of	, 2015.
	Notary Public	W DANAGA .
	Notary Fublic	
My commission expires on:		

REQUESTS FOR PRODUCTION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On February 23, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to UniFirst Corporation.* In order to minimize the impact of discovery on UniFirst, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-23** from the *Saint Thomas Entities' First Set of Requests for Production.* The "new" requests begin at Number 24.

1-23. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-23 from the *Saint Thomas Entities' First Set of Requests for Production*.]

ANSWER:

REQUESTS FOR PRODUCTION

24. Produce all documents not yet produced referring or related to any contamination in or around the NECC cleanrooms.

ANSWER:

25. Produce the customer file for Ameridose.

ANSWER:

26. Produce every document request from the PSC and every response given.

ANSWER:

27. Produce each and every document produced during mediation.

REQUESTS FOR ADMISSION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On February 23, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to UniFirst Corporation.* In order to minimize the impact of discovery on UniFirst, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-19** from the *Saint Thomas Entities' First Set of Requests for Admission.* The "new" requests begin at Number 20.

1-19. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-19 from the Saint Thomas Entities' First Set of Requests for Admission.]

RESPONSE:

REQUESTS FOR ADMISSION

- 20. Admit that the following acts¹, if the proof establishes that they occurred, constitute breaches of UniFirst's duty to act with reasonable care when cleaning NECC²:
 - a. Cleaning personnel entered the NECC cleanrooms (including the anterooms) in street clothes, without donning sterile or contaminant-free garments such as shoe covers, hair caps, coveralls, and gloves.³
 - b. Cleaning personnel brought in and used in the NECC cleanrooms cleaning equipment (including mops, mop heads, sponges, and buckets) that had previously been used outside of the NECC facility.⁴
 - c. Cleaning personnel brought in and used in the NECC cleanrooms cleaning equipment (including mops, mop heads, sponges, and buckets) that had previously been used in other portions of the NECC facility that did not constitute cleanrooms.⁵
 - d. Cleaning personnel did not sanitize all cleaning equipment (including mops, mop heads, sponges, and buckets) that had been used outside of the NECC facility before bringing them into the NECC cleanrooms.⁶

¹ These are the acts described in Requests for Admission 1-19.

² These should be answered individually if some of the responses are denials.

[°] RFA 13.

⁴ RFA 14 and 15. (These are duplicates.)

⁵ RFA 16.

⁶ RFA 17.

e. Cleaning personnel failed to clean or wipe shoes, boots, or other footwear on floor mats placed at NECC cleanroom entry points before entering the cleanrooms.⁷

RESPONSE:

- 21. Admit that the following acts, if the proof establishes that they occurred, increased the probability that unwanted contaminants would be introduced into the cleanroom environment⁸:
 - a. Cleaning personnel entered the NECC cleanrooms (including the anterooms) in street clothes, without donning sterile or contaminant-free garments such as shoe covers, hair caps, coveralls, and gloves.
 - b. Cleaning personnel brought in and used in the NECC cleanrooms cleaning equipment (including mops, mop heads, sponges, and buckets) that had previously been used outside of the NECC facility.
 - c. Cleaning personnel brought in and used in the NECC cleanrooms cleaning equipment (including mops, mop heads, sponges, and buckets) that had previously been used in other portions of the NECC facility that did not constitute cleanrooms.
 - d. Cleaning personnel did not sanitize all cleaning equipment (including mops, mop heads, sponges, and buckets) that had been used outside of the NECC facility before bringing them into the NECC cleanrooms.
 - e. Cleaning personnel failed to clean or wipe shoes, boots, or other footwear on floor mats placed at NECC cleanroom entry points before entering the cleanrooms.

RESPONSE:

⁷ RFA 19

⁸ These should be answered individually if some of the responses are denials.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of March, 2015, a true and accurate copy of the foregoing was served on UniFirst by U.S. Mail and on the other parties electronically via the Court's CM/ECF system.

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Attorneys for the Saint Thomas

Entities

/s/ Chris J. Tardio

Chris J. Tardio

DISCOVERY TO ALAUNUS

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

United States District Court for the DISTRICT OF MASSACHUSETTS IN RE NECC PRODUCTS LIAB. LIT. (MDL) Plaintiff Civil Action No. MDL NO. 2419; 1:13-md-2419 ALL CASES AGAINST TENNESSEE DEFENDANTS Defendant SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION ALAUNUS PHARMACEUTICAL, LLC To: (Name of person to whom this subpoena is directed) Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: Documents identified in the attached list. Date and Time: To be designated by Alaunus 04/27/2015 9:00 am ☐ Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it. Date and Time: Place: The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so. 03/20/2015 Date: CLERK OF COURT OR Signature of Clerk or Deputy Clerk Attorney's signature The name, address, e-mail address, and telephone number of the attorney representing (name of party) , who issues or requests this subpoena, are: Tennessee Clinic Defendants

Notice to the person who issues or requests this subpoena

Chris J. Tardio, 315 Deaderick Street, Ste. 1100, Nashville, TN 37219; 615-254-0400; chris@gideoncooper.com

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

EXHIBIT

[DUCES TECUM TO ALAUNUS]

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

:13-md-2419-RWZ

THE TENNESSEE CLINIC DEFENDANTS' NOTICE OF REQUESTED DOCUMENTS (DUCES TECUM) WITH SUBPOENA TO ALAUNUS PHARMACEUTICALS

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure, serve this list of requested documents to accompany the subpoena contemporaneously issued.

On March 9, 2015, the Saint Thomas Entities served their Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action and Requests for Production on Alaunus Pharmaceuticals ("Alaunus"). In order to minimize the impact on Alaunus created by having to respond to multiple sets of discovery, the Tennessee Clinic Defendants hereby adopt and incorporate the subpoena duces tecum served by the Saint Thomas Entities with slight modification.

INSTRUCTIONS AND DEFINITIONS

The Tennessee Clinic Defendants adopt and incorporate as if stated fully herein the preamble and "Instructions and Definitions" sections of the Saint Thomas Entities' Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action and Requests for Production on Alaunus.

NOTICE OF REQUESTED DOCUMENTS

In order to minimize the impact of discovery on Alaunus, these Tennessee Clinic Defendants hereby adopt and incorporate, as if stated fully herein, the following Requests for Production Saint Thomas Entities Requests for Production:

RFP 1 RFP 2 RFP 3 RFP 5 RFP 6 RFP 7 RFP 11 RFP 12 RFP 13 RFP 14 RFP 15.

The Tennessee Clinic Defendants also request:

1. Any and all documents related to complaints lodged against Alaunus prior to the meningitis outbreak for the conduct of its managers – Gregory Conigliaro and Barry Cadden – in operating the facility in compliance with state and federal law and industry standards.

RESPONSE:

2. Any and all documents related to any actions, warnings, or reprimands by any regulatory agency prior to the meningitis outbreak for the conduct of Gregory Conigliaro or Barry Cadden in operating Alaunus.

RESPONSE:

3. Any and all documents related to the sale, use, or disposal of stock solutions that are past or approaching their beyond-use date.

RESPONSE:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

CERTIFICATE OF SERVICE

I certify that this document was served on Alaunus Pharmaceutical's registered agent via email, was filed through the CM/ECF system, will be served electronically to the registered participants identified on the Notice of Electronic Filing, and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 20th day of March, 2015.

/s/ Chris J. Tardio Chris J. Tardio

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/s/ Chris J. Tardio

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DISCOVERY TO AMERIDOSE

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)) MDL No. 2419) Dkt. No. 1:13-md-2419-RWZ)
This Document Relates to Suits Naming: Suits Naming the Tennessee Clinic Defendants))))

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO AMERIDOSE, LLC.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Ameridose, LLC ("LLC").

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

- 1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.
- 2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.
- 3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.
- 4. "You" and "your" refers to Ameridose and each of its present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on its behalf.
- 5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and the copy of the document;
- D. State in as much detail as possible the contents of the documents; and
- E. State the manner and date of disposition of the document.

If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and a copy of the document;
- D. State the subject matter of the document; and
- E. State the basis upon which you contend you are entitled to withhold the document from production.
- 2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.
- 3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

- 4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."
- 5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.
- 6. The singular should be construed to include the plural, and the plural should be construed to include the singular.
- 7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.
- 8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Ameridose, LLC.* In order to minimize the impact of discovery on Ameridose, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-11** from the *Saint Thomas Entities' First Set of Interrogatories.* The "new" interrogatories begin at Number 12.

1-11. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-11 from the *Saint Thomas Entities' First Set of Interrogatories*.]¹

ANSWER:

INTERROGATORIES

12. Identify the specific areas of the NECC facility that Ameridose used in 2012, including any cleanrooms, and describe the nature and extent of Ameridose's activity at the NECC facility in 2012.

ANSWER:

13. Identify any and all complaints Ameridose received related to the sterility or safety of its products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

ANSWER:

14. Identify any and all complaints Ameridose received related to its compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

¹ In Interrogatory Number 6 from the Saint Thomas Entities' First Set of Interrogatories, "mediation" should instead be "medication."

15. Describe all disciplinary or enforcement action taken against Ameridose by any state or federal government agency.

VERIFICATION

STATE OF TENNESSEE)		
COUNTY OF)		
	l l marke	- the theat the foregoing
I,, after being duly	sworn, hereby make o	path that the loregoing
answers to interrogatories are true to the be	st of my knowledge, info	ormation, and belief.
		0045
Sworn to and subscribed before me this	day of	, 2015.
	Nota	ary Public
• • · · · · · · · · · · · · · · · · · ·		
My commission expires on:	•	

REQUESTS FOR PRODUCTION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Ameridose, LLC.* In order to minimize the impact of discovery on Ameridose, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-33** from the *Saint Thomas Entities' First Set of Interrogatories.* The "new" Requests for Production begin at Number 34.

1-33. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-33 from the Saint Thomas Entities' First Requests for Production.]

ANSWER:

REQUESTS FOR PRODUCTION

34. Produce all correspondence between Ameridose and any of the Tennessee Clinic Defendants, their employees, agents, or representatives.

ANSWER:

35. Produce all internal correspondence or documents referring or relating to the Tennessee Clinic Defendants' purchase of MPA from NECC in 2012.

ANSWER:

36. Produce any and all documents related to the sale, use, or disposal of stock solutions that are passed or approaching their beyond-use date.

ANSWER:

37. Produce all document requests from the PSC and every response given.

ANSWER:

REQUESTS FOR ADMISSION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Ameridose, LLC.* In order to minimize the impact of discovery on Ameridose, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-15** from the *Saint Thomas Entities' First Set of Requests for Admission.* The "new" requests begin at Number 16.

REQUESTS FOR ADMISSIONS

1-15. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-15 from the Saint Thomas Entities' First Requests for Admission.]

ANSWER:

17. Admit that, had any of the Tennessee Clinic Defendants asked for a copy of Ameridose's license in 2011, Ameridose would have provided a valid and up-to-date Massachusetts pharmacy license.

ANSWER:

18. Admit that, had any of the Tennessee Clinic Defendants asked Ameridose about its sterility standards in 2011, Ameridose would have stated that it met or exceeded USP 797 standards.

ANSWER:

19. Admit that, had had any of the Tennessee Clinic Defendants asked Ameridose whether it was a registered manufacturer, Ameridose would have stated that it was registered as a manufacturer with both the FDA and DEA.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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Attorneys for the Tennessee Clinic Defendants

^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of March, 2015, a true and accurate copy of the foregoing was served on Ameridose by U.S. Mail and on the other parties below electronically via the Court's CM/ECF system:

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Attorneys for the Saint Thomas

Entities

/s/ Chris J. Tardio

Chris J. Tardio

DISCOVERY TO ARL

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)) MDL No. 2419) Dkt. No. 1:13-md-2419-RWZ)
This Document Relates to Suits Naming:))
Suits Naming the Tennessee Clinic Defendants	,))

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO ARL BIO PHARMA, INC. d/b/a ANALYTICAL RESEARCH LABORATORIES

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories and Requests for Production of Documents, and Requests for Admission to ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL").

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

- 1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.
- 2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.
- 3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.
- 4. "You" and "your" refers to ARL and each of its present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on its behalf.
- 5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and the copy of the document;
- D. State in as much detail as possible the contents of the documents; and
- E. State the manner and date of disposition of the document.

If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and a copy of the document;
- D. State the subject matter of the document; and
- E. State the basis upon which you contend you are entitled to withhold the document from production.
- 2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.
- 3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

- 4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."
- 5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.
- 6. The singular should be construed to include the plural, and the plural should be construed to include the singular.
- 7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.
- 8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to ARL Bio Pharma, Inc.* In order to minimize the impact of discovery on ARL, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-15** from the *Saint Thomas Entities' First Set of Interrogatories*. The "new" interrogatories begin at Number 16.

1-15. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-15 from the Saint Thomas Entities' First Set of Interrogatories.]

ANSWER:

INTERROGATORIES

16. Identify and describe (1) when ARL began providing testing services to New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") and Ameridose, LLC ("Ameridose"); (2) whether there were any breaks in the period of time that ARL provided testing services (and, if so, when and why); (3) the scope of ARL's work (e.g., to test all medications; to test just certain medications; to only provide certain testing services; etc.); (4) the frequency with which ARL provided those services (e.g., once monthly; once weekly; daily; etc.); and (5) the nature of the services (i.e., what specific testing services ARL provided).

ANSWER:

17. Identify by name and job title all of your officers, agents, employees, representatives, and contractors who acted as an account manager for NECC or were otherwise designated to NECC's account.

ANSWER:

18. Describe in detail ARL's procedures for testing NECC's MPA that ARL received for lot numbers 052122012@68, 06292012@26, and 08102012@51 ("Contaminated Lots"), including:

- a. When each lot was tested;
- b. All measures ARL took to comply with USP 71 when performing sterility testing;
- c. When ARL certified each lot as sterile and free of fungal contamination; and
- d. Whether ARL kept an inventory of the samples it received for testing.

ANSWER:

19. Identify the total size of each lot of NECC's MPA that ARL has tested since January 1, 2010.

ANSWER:

20. Describe in detail the "meticulous analysis, data interpretation, and troubleshooting" that ARL provided to compounding pharmacies in 2012, as advertised on ARL's website, a printout of which is attached as Exhibit A.

ANSWER:

- 21. Describe in detail ARL's "alternative method specifically designed for examining products required to be sterile for fungal microorganisms" that ARL advertised on its website in 2012, a printout of which is attached as Exhibit C. Please identify and describe with particularity:
 - a. The "selective media specifically designed for the growth of fungal contamination" referenced in Exhibit C;
 - b. The "selective properties, lower pH and high dextrose concentration" described in Exhibit C; and
 - c. How the selective media "targets the recovery of fungal contaminants by inhibiting the growth of bacteria," as described in Exhibit C.

ANSWER:

22. Identify every instance in which NECC submitted samples of medications for testing that were inadequate for compliance with USP standards, including but not limited to an insufficient number of samples or insufficient sample volume.

ANSWER:

23. For each instance identified in Interrogatory Number 12, identify any and all communications between ARL and NECC regarding the insufficient samples and whether ARL requested additional samples.

ANSWER:

24. Describe in detail "Sterility Testing MBI-144," ARL's "internal method" that ARL advertised on its website in 2012, a printout of which is attached as Exhibit B. Include any way in which the Sterility Testing MBI-144 differed from USP 71-compliant testing in 2012.

ANSWER:

25. Identify the number of times, the dates, and medications on which ARL used "Sterility Testing MBI-144" for NECC products.

ANSWER:

VERIFICATION

STATE OF TENNESSEE)		
COUNTY OF)		
I,, after being duly	y sworn, hereby make	e oath that the foregoing
answers to interrogatories are true to the b	pest of my knowledge,	information, and belief.
Sworn to and subscribed before me this _	day of	, 2015.
	N	otary Public
My commission expires on:		

REQUESTS FOR PRODUCTION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their First Set of Interrogatories, Requests for Production, and Requests for Admission to ARL BioPharma, Inc. In order to minimize the impact of discovery on ARL, these Tennessee Clinic Defendants hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-17 from the Saint Thomas Entities' First Set of Requests for Production. The "new" requests begin at Number 18.

1-17. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-17 from the Saint Thomas Entities' First Set of Requests for Production.]

RESPONSE:

REQUESTS FOR PRODUCTION

18. Produce all documents or correspondence with any party referring or relating to NECC or Ameridose submitting an insufficient amount of sample material(s) for sterility or fungal testing.

RESPONSE:

19. Produce all documents or correspondence with any party referring or relating to NECC or Ameridose products that failed sterility or fungal testing at any time.

RESPONSE:

20. Produce all correspondence between ARL and NECC about the Contaminated Lots, including but not limited to, communications after the meningitis outbreak.

RESPONSE:

21. Produce every document request from the PSC and every response given.

RESPONSE:

22. Produce each and every document produced during mediation.

RESPONSE:

REQUESTS FOR ADMISSION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to ARL BioPharma, Inc.* In order to minimize the impact of discovery on ARL, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-17** from the *Saint Thomas Entities' First Set of Requests for Admission.* The "new" requests begin at Number 18.

REQUESTS FOR ADMISSIONS

18. ARL's CEO is Thomas Kupeic, PhD.

ANSWER:

19. In 2007, Thomas Kupeic, PhD. coauthored an article entitled "Quality Control Analytical Methods: The Quality of Sterility Testing," which was published in the International Journal of Pharmaceutical Compounding.¹

ANSWER:

20. The article referenced in Request for Admission Number 19 and attached as Exhibit E states in part:

"Care must be taken during the compounding process to ensure that the preparation being made is of the highest quality, and microbiology testing is no exception. On a daily basis, quality-control laboratories are on the front line of testing newly formed preparations. With each new drug tested, there is a great responsibility that everything possible is done to ensure that the test result reported is accurate and reliable."

ANSWER:

21. In 2012, ARL certified NECC MPA lots 052122012@68, 06292012@26, and 08102012@51 ("Contaminated Lots") as sterile.

ANSWER:

² Exhibit E, p. 4.

¹ McGuire, Jason & Kupiec, Thomas C., Quality Control Analytical Methods: The Quality of Sterility Testing, <u>Int'l J. Pharm. Comp.</u>, 2007, Jan-Feb; 11(1), 52, 55. Attached as Exhibit E.

22. ARL did not report contamination in any lots of MPA tested in 2012 from NECC or Ameridose to NECC or any other party.

ANSWER:

23. Had a customer asked for the sterility testing results for any of the Contaminated Lots, he or she would have received a report from ARL indicating the product was sterile.

ANSWER:

24. Samples of MPA that NECC sent to ARL for testing were of inadequate size or volume to comply with USP 71.

ANSWER:

25. ARL did not notify NECC when NECC sent samples of MPA for testing that were of inadequate size or volume to comply with USP 71.

ANSWER:

26. ARL did not notify any other party or regulatory agency when NECC sent samples of MPA for testing that were of inadequate size or volume to comply with USP 71.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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Chris J. Tardio*
Alan S. Bean**
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Attorneys for the Tennessee Clinic Defendants

^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of March, 2015, a true and accurate copy of the foregoing was served on ARL by U.S. Mail and on the other parties below electronically via the Court's CM/ECF system:

Gerard Stranch, IV Ben Gastel Branstetter, Stranch & Jennings, PLLC 227 2nd Ave N Suite 400 Nashville, TN 37201 Attorneys for the PSC [via hand-delivery, to upload to repository]	Matthew P. Moriarty Thomas W. Coffey Richard A. Dean Tucker Ellis, LLP 950 Main Avenue, Suite 1100 Cleveland, OH 44113 Scott H. Kremer Tucker, Heifetz & Saltzman Three School Street Boston, MA 02108
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Daniel M. Rabinovitz Brady J. Hermann Nicki Samson Michaels, Ward & Rabinovitz One Beacon Street, 2nd Floor Boston, MA 02108 Attorneys for Defendant Medical Sales Management, Inc.	John P. Ryan Robert H. Gaynor William J. Dailey, Jr. Sloane and Walsh, LLP Three Center Plaza Boston, MA 02108 Attorneys for Gregory Conigliaro, Registered Agent for Service of Process for Medical Sales Management SW, Inc.

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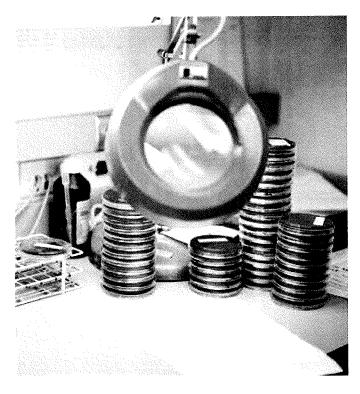
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/s/ Chris J. Tardio

Chris J. Tardio

EXHIBIT E



QUALITY-CONTROL ANALYTICAL METHODS: THE QUALITY OF STERILITY TESTING

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Abstract

Microbiology, like compounding, is a science that must be demonstrated to show that it is reliable, reproducible, and scientifically sound. Aseptic technique must become second nature to the microbiologist and the compounding pharmacist. With each new drug tested by a quality-control laboratory, there is a responsibility that everything possible is done to ensure that the test result reported is accurate and reliable. While it is recognized that the conventional sterility-testing method has inherent deficiencies, an alternative method cannot be used unless it provides equivalent assurance of detecting microbial contamination. A quality-control laboratory and compounding pharmacists should adhere to the standards of the United States Pharmacopeia when compounding and testing preparations.

It is easy to become complacent with our habits, whether those habits are good or bad. Bad medical habits, however, can lead to detrimental health conditions and untimely deaths. In 1847, when Vienna, Austria, was considered the world's leading medical center, physician Ignaz Semmelweis discovered by simple observation the cause of puerperal fever, then known as childbed fever. Semmelweis implemented a solution, and, in 3 months, the death rate in the maternity ward fell from 18% to 1%. Semmelweis' solution was simple—he ordered doctors and medical students to wash their hands. He deter-

mined that a doctor going from patient to patient without handwashing could carry and spread puerperal fever, which today is known to be caused by *Streptococcus pyogenes*. Although his findings were published and even duplicated, nobody listened. It would be many years and thousands more deaths before handwashing became accepted clinical practice.

Those involved in quality control are also subject to complacency. Quality-control methods often are accepted because "that's the way it has always been done." This is an especially dangerous attitude if the test result is biased or based on the

conditions set forth, or if a better method is overlooked. A quality-control laboratory has a great responsibility to not only adhere to the guidelines, but to continually examine its employees and methods, and should refer to the literature critical to the field involved; microbiological testing is no exception.

Microbial testing in pharmaceutical compounding should be examined in two parts: (1) process validation and (2) end-preparation sterility testing. *United States Pharmacopeia (USP)* Chapter <797> outlines process validation in the sections titled "Personnel Training and Evaluation in Aseptic Manipulation Skills" and "Environmental Quality and Control." End-preparation sterility testing falls under the "Finished Preparation Release Checks and Tests" section. ¹ Each section is important, but the focus here is only on sterility testing.

History

Since the inauguration of sterility testing in 1936, great improvements have been made in our ability to detect microbial contamination in pharmaceutical compounds. When sterility testing was

introduced, in USP-National Formulary (NF) 11, it was recommended only for liquid preparations and required only a 7-day incubation period and one type of culture medium. Over the 70 years since USP-NF 11 was published, USP sterility testing methods and the media recommended have been revised frequently in ongoing attempts to improve the detection of microbiological contamination. Today, USP Chapter <71> requires the use of two culture media, Soybean-Casein Digest Medium (SCDM) and Fluid Thioglycollate Medium (FTM), and a 14-day incubation period.1

Sterility Testing

USP Chapter <71> states that "...sterility testing is a very exacting procedure, where asepsis of the procedure must be ensured for a correct interpretation of results...." The USP also states that alternative methods may be utilized as long as they are validated and "will yield results equivalent to, or better than, the results generated by the conventional method."1

Although the compendial sterility testing is the most widely accepted method, it has inherent limitations. 2-6 In a review published in the Pharmacopeial Forum, the United States Pharmacopeial (USP) Expert Committee responsible for USP Chapter <71> Sterility Testing examined the media and incubation conditions recommended for compendial sterility testing.4 Through this review, deficiencies were recognized and recommendations made, some of which are discussed in this article.

Limitations to Compendial Sterility Testing

Sample Size

One of the recognized limitations of sterility testing is sample size. 1,5,6 USP Chapter <1211> notes that "the referee sterility test might not detect microbial contamination if present in only a small percentage of the finished articles in the lot because the specified number of units to be taken imposes a significant statistical limitation on the utility of the test results."1 Since the absolute sterility of a preparation lot cannot be demonstrated without complete destruction of every

article, and there are other limitations of the sterility testing itself, everything possible must be done to ensure that the preparation is safe to dispense. This would include ensuring that the sterilization process and aseptic processing procedures are validated and personnel properly trained and qualified for compounded sterile preparations. The compounding pharmacy should verify that its preparations are free of microbial contamination.

Testing Conditions

It is vital that a detection procedure be in place in case contamination occurs. Currently, USP Chapter <71> states that SCDM and FTM should be incubated at $22.5^{\circ} \pm 2.5^{\circ}$ C and $32.5^{\circ} \pm 2.5^{\circ}$ C, respectively. SCDM is used for promoting the growth of aerobic bacteria and fungi, while FTM is used primarily for anaerobes but will grow some aerobes. Both the primary and secondary literature have shown,

however, that these are less than optimal growth conditions for many bacteria and fungi.2,4,6-8

While the recommended temperature of 22.5° ± 2.5°C for SCDM may be aimed at detecting environmental contamination, it has been well documented that most clinically significant bacteria grow at temperatures between 25°C and 40°C and fungi at temperatures between 25°C and 30°C.7,8 The manufacturers of the fungal growth medium recommended in the USP recommends incubation temperatures in the range from 25°C to 30°C.9 One of the recommendations made by the USP **Expert Committee for Sterility Testing** was to increase the incubation temperature to $27.5^{\circ} \pm 2.5^{\circ}$ C to optimize the recovery of bacteria, yeasts, and molds-a change that has yet to occur.4

A comprehensive study of the growthpromoting characteristics of seven different media examined 88 different



strains of bacteria, 38 strains of yeast, and 54 strains of mold.² This study concluded that SCDM and FTM were less effective than dithionite-thioglycollate broth (HS-T) at growing both aerobic and anaerobic bacteria when incubated at 32°C. It was also shown that SCDM was less effective in promoting growth of fungi and yeasts than four other media when incubated at 26°C for 10 days. The four media were Sabouraud Liquid Medium, Sabouraud Dextrose Agar, Peptone Liver Digest Broth, and Peptone Liver Digest Agar.

USP Chapter <61> Microbial Limit Tests states that Sabouraud Dextrose Agar Medium or Potato Dextrose Agar Medium should be used instead of SCDM for performing total combined counts of molds and yeasts.¹

While the addition of another growthpromoting medium adds more cost to the sterility-testing process, a risk assessment should be performed. Special consideration should be given to the environmental quality of the compounding facility, taking into account humidity levels, temperature, and the type of organisms that have been isolated from the compounding area. If these variables are unknown, an inexpensive thermometer and hygrometer combination device can be purchased, as can pre-made media for testing for organisms in the environment. Using media specific for bacteria and fungi, the compounding area should be sampled, using contact plates, settling plates, or an air sampler to determine the type and extent of contamination that may exist. USP Chapter <797> offers information for key areas to examine and how often they should be tested.

Another area of discussion is the methods employed for sterility testing, which are (1) membrane filtration and (2) direct inoculation. Some advantages of the membrane filtration method are

the ability to test more sample using less medium, fewer false positives, and greater sensitivity than the direct inoculation technique. These advantages also could be cited for direct inoculation if a validated alternative method is used with the right incubation conditions and appropriate growth medium.

The 7-day incubation period was at one time thought sufficient for preparations tested by membrane filtration because it was theorized that the antimicrobial properties would be removed through the filtering process and growth would occur earlier. This requirement was changed to a 14-day incubation period in USP-NF 24, the same as was prescribed for direct inoculation. This change was implemented on the recommendation of the USP following emergence of a growing body of evidence that an unacceptable amount of growth was occurring after the 7-day incubation period.^{3,4} It was also demonstrated that, for the preparations tested, there was no significant difference in rates of detection of positives between the direct inoculation method and the membrane filtration method after 14 days of incubation.3

Another study concluded that solid media were effective growth-promotion materials, and, in some cases, growth was observed 1 to 2 days earlier in solid media than in broth. This 1- to 2-day lead time can be crucial in identifying and correcting contamination problems to minimize compounding down time. In the case of hospital compounding, where many times compounds have to be made and dispensed the same day, the earlier a breakdown in the aseptic process is detected, the quicker the medical staff can notify the patients affected and begin monitoring the patients for adverse events.

Looking Ahead at Sterility Testing The Future

Many times quality-control laboratories view alternative methods as "taboo." This may be warranted if the methods haven't been validated against the standard of *USP* Chapter <71>. Furthermore, while the industry may never change the 14-day sterility testing incubation requirement, there



still must be an effort to improve early detection of microbial contamination. Rapid microbiological analysis is still relatively new in the pharmaceutical industry, and there are several new products and methodologies, using more sensitive biological markers, that could be employed in the compounding setting.⁶

The U.S. Food and Drug Administration encourages the pharmaceutical industry to use new technologies that will allow for real-time quality assurance. With the advent of new technologies and methodologies, the opportunity for preparations to be released in days instead of weeks has been recognized. A more comprehensive overview of the pros and cons of the new methods on the horizon and an appropriate validation protocol is available from articles written by Moldenhauer and Sutton, Riley, 11 and Sutton. 12

Conclusion

Microbiology, like compounding, is a science that must be demonstrated to show that it is reliable, reproducible, and scientifically sound. Aseptic technique must become second nature to the microbiologist and compounder and, as they teach in graduate school, those involved in the sciences must begin to "think like the bugs." Care must be taken during the compounding process to ensure that the preparation being made is of the highest quality, and microbiological testing is no exception. On a daily basis, quality-control laboratories are on the front line of testing newly formulated preparations. With each new

drug tested, there is a great responsibility that everything possible is done to ensure that the test result reported is accurate and reliable. While it is recognized that the conventional sterility-testing method has inherent deficiencies, an alternative method cannot be used unless it provides equivalent assurance of detecting microbial contamination.

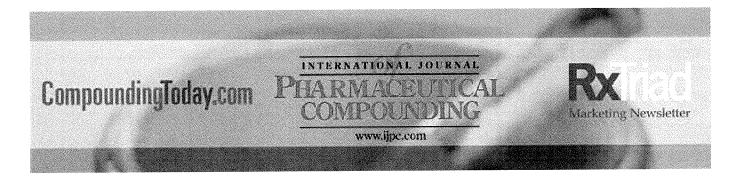
Too many times, quality-control laboratories get caught up in the old adage "if it ain't broke, don't fix it." Often, it is not just that something is "broken," but that it can be improved. Imagine if Dr. Semmelweis hadn't decided to make a difference; it would have been easier for him to keep going along like everything was fine. Quality-control laboratories should think the same way and want to make a difference.

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DISCOVERY TO LIBERTY

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)) MDL No. 2419) Dkt. No. 1:13-md-2419-RWZ)
This Document Relates to:))
Suits Naming the Tennessee Clinic Defendants	,))
)

THE TENNESSEE CLINIC DEFENDANTS' FIRST INTERROGATORIES AND REQUESTS FOR PRODUCTON OF DOCUMENTS AND REQUESTS FOR ADMISSION PROPOUNDED TO LIBERTY INDUSTRIES, INC.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Liberty Industries, Inc. ("Liberty").

On March 9, 2015, the Saint Thomas Entities served their *First Set of Interrogatories, Requests for Production, and Requests for Admission* on Liberty. In order to minimize the impact on Liberty created by having to respond to multiple sets of discovery, the Tennessee Clinic Defendants hereby adopt and incorporate the set of discovery served by the Saint Thomas Entities.

INSTRUCTIONS AND DEFINITIONS

The Tennessee Clinic Defendants adopt and incorporate as if stated fully herein the preamble and "Instructions and Definitions" sections of the Saint Thomas Entities' *First Set of Interrogatories, Requests for Production, and Requests for Admission* to Liberty.

INTERROGATORIES ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

In order to minimize the impact of discovery on Liberty, these Tennessee Clinic Defendants hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-10 from the Saint Thomas Entities' First Set of Interrogatories to Liberty.

1-10. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-10 from the Saint Thomas Entities' First Set of Interrogatories to Liberty.]

ANSWER:

VERIFIC	CATION		
STATE OF) COUNTY OF)			
I,, after being duly s	worn, hereby ma	ke oath that the fore	going
answers to interrogatories are true to the bes	t of my knowledge	, information, and belie	∋f.
Sworn to and subscribed before me this	day of	, 201	15.
		Notary Public	

My commission expires on:

REQUESTS FOR PRODUCTION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY ST. THOMAS ENTITIES

In order to minimize the impact of discovery on Liberty, these Tennessee Clinic Defendants hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-33 from the Saint Thomas Entities' First Set of Requests for Production to Liberty.

1-33. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-33 from the Saint Thomas Entities' First Set of Requests for Production to Liberty.]

ANSWER:

REQUESTS FOR ADMISSION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

In order to minimize the impact of discovery on Liberty, these Tennessee Clinic Defendants hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-18 from the Saint Thomas Entities' First Set of Requests for Admission to Liberty.

1-18. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-18 from the Saint Thomas Entities' First Set of Requests for Admission to Liberty.]

RESPONSE:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of March, 2015, a true and accurate copy of the foregoing was served on Liberty Industries, Inc. by U.S. Mail and on the other parties electronically via the Court's CM/ECF system:

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Chris J. Tardio

DISCOVERY TO MSM

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)) MDL No. 2419) Dkt. No. 1:13-md-2419-RWZ)
This Document Relates to Suits Naming:))
Suits Naming the Tennessee Clinic Defendants	,))
)

THE TENNESSEE CLINIC DEFENDANTS'
FIRST INTERROGATORIES, REQUESTS FOR PRODUCTON OF DOCUMENTS,
AND REQUESTS FOR ADMISSION PROPOUNDED TO MEDICAL SALES
MANAGEMENT, INC. AND MEDICAL SALES MANAGEMENT SW, INC.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Medical Sales Management, Inc. ("MSM") and Medical Sales Management SW, Inc. ("MSMSW").

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

- 1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.
- 2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.
- 3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.
- 4. "You" and "your" refers to MSM and MSMSW and each of their present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on their behalf.
- 5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and the copy of the document;
- D. State in as much detail as possible the contents of the documents; and
- E. State the manner and date of disposition of the document.

If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and a copy of the document;
- D. State the subject matter of the document; and
- E. State the basis upon which you contend you are entitled to withhold the document from production.
- 2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.
- 3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

- 4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."
- 5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.
- 6. The singular should be construed to include the plural, and the plural should be construed to include the singular.
- 7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.
- 8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY SAINT THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to MSM and MSMSW.* In order to minimize the impact of discovery on MSM and MSMSW, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-5** from the *Saint Thomas Entities' First Set of Interrogatories.* The "new" interrogatories begin at Number 6.

1-5. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-5 from the Saint Thomas Entities' First Set of Interrogatories.]

ANSWER:

INTERROGATORIES

6. Identify all of MSM and MSMSW's employees, their job titles, the date they started at MSM or MSMSW, the date they left MSM or MSMSW, the sales territories to which they were assigned in 2011 and 2012, and their last known home address, telephone number, and personal email address.

ANSWER:

7. Describe the specific location where MSM and MSMSW were located in relation to the NECC facility, and describe the total percentage of the facility they occupied.

ANSWER:

8. Describe in detail the manner in which MSM and MSMSW's officers, employees, and agents were compensated (salary, hourly wages, commission, bonus structure, whether compensation varied by product, etc.).

ANSWER:

VERIFICATION

STATE OF TENNESSEE)			
COUNTY OF)			
I,, after be	eing duly sv	vorn, hereby	make oath that the	foregoing
answers to interrogatories are true	e to the best	of my knowle	dge, information, and	d belief.
Sworn to and subscribed before n	ne this	_day of		_, 2015.
			Notary Public	
My commission expires on:				

REQUESTS FOR PRODUCTION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY ST. THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to MSM and MSMSW.* In order to minimize the impact of discovery on MSM and MSMSW, these Tennessee Clinic Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-14** from the *Saint Thomas Entities' First Requests for Production.* The "new" Requests for Production begin at Number 15.

1-14. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-14 from the Saint Thomas Entities' First Requests for Production.]

ANSWER:

REQUESTS FOR PRODUCTION

15. Produce all correspondence between MSM, MSMSW, and any of the Tennessee Clinic Defendants.

RESPONSE:

16. Produce any internal correspondence or documents referring or relating to any of the Tennessee Clinic Defendants.

RESPONSE:

17. Produce all internal policies, procedures, or guidelines that governed how NECC products were marketed to customers in 2011 and 2012.

RESPONSE:

18. Produce any documents or correspondence referring or relating to how MSM and MSMSW's sales personnel, employees, or agents were to sell or market NECC's products to any of the Tennessee Clinic Defendants.

RESPONSE:

19. Produce every document request from the PSC and every response given.

RESPONSE:

20. Produce each and every document produced during mediation.

RESPONSE:

REQUESTS FOR ADMISSION ADOPTED AND INCORPORATED FROM DISCOVERY SENT BY ST. THOMAS ENTITIES

On March 9, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to MSM and MSMSW.* In order to minimize the impact of discovery on MSM and MSMSW, these Tennessee Clinic Defendants hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-32 from the *Saint Thomas Entities' First Requests for Admission*. The "new" requests begin at Number 33.

REQUESTS FOR ADMISSIONS

1-32. [The Tennessee Clinic Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-32 from the Saint Thomas Entities' First Requests for Admission.]

ANSWER:

33. MSM represented to Jean Atkinson that MPA compounded by NECC met the requirements of USP 797.

ANSWER:

34. MSM represented to Jean Atkinson that MPA compounded by NECC was safe and reliable.

ANSWER:

35. MSM represented to Jean Atkinson that the Massachusetts Board of Pharmacy permitted the sale of compounded medications without prescriptions so long as a patient list was provided to NECC.

ANSWER:

36. MSM represented to Debra Schamberg that it was necessary for her to send a list of patient names to comply with Massachusetts law.

ANSWER:

37. MSM represented to Jean Atkinson that it was necessary for her to send a list of patient names to comply with Massachusetts law.

ANSWER:

38. MSM did not instruct Jean Atkinson to send individual, patient-specific prescriptions to NECC when purchasing MPA.

ANSWER:

39. MSM did not instruct Debra Schamberg to send individual, patient-specific prescriptions to NECC when purchasing MPA.

ANSWER:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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Attorneys for the Tennessee Clinic Defendants

^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of March, 2015, a true and accurate copy of the foregoing was served on Medical Sales Management and Medical Sales Management SW by U.S. Mail and on the other parties below electronically via the Court's CM/ECF system:

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Attorneys for the Saint Thomas Entities

/s/ Chris J. Tardio

Chris J. Tardio

DISCOVERY TO VICTORY

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the DISTRICT OF MASSACHUSETTS IN RE NECC PRODUCTS LIAB. LIT. (MDL) Plaintiff Civil Action No. MDL NO. 2419; 1:13-md-2419 ALL CASES AGAINST TENNESSEE DEFENDANTS Defendant SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION VICTORY HEATING AND AIR CONDITIONING CO., INC. / VICTORY MECHANICAL SERVICES, INC. To: (Name of person to whom this subpoena is directed) YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: Documents identified in the attached list. Date and Time: Place: To be designated by Victory 04/27/2015 9:00 am ☐ Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it. Date and Time: Place: The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so. 03/20/2015 Date: CLERK OF COURT OR Attorney's signature Signature of Clerk or Deputy Clerk The name, address, e-mail address, and telephone number of the attorney representing (name of party)

Notice to the person who issues or requests this subpoena

Chris J. Tardio, 315 Deaderick Street, Ste. 1100, Nashville, TN 37219; 615-254-0400; chris@gideoncooper.com

Tennessee Clinic Defendants

, who issues or requests this subpoena, are:

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

EXHIBIT

[DUCES TECUM TO VICTORY]

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION) MDL No. 2419) Dkt. No. 1:13-md-2419-RWZ)
This Document Relates to:))
Suits Naming the Tennessee Clinic Defendants)))

THE TENNESSEE CLINIC DEFENDANTS'
NOTICE OF REQUESTED DOCUMENTS (DUCES TECUM) WITH SUBPOENA TO
VICTORY HEATING AND AIR CONDITIONING CO., INC.
AND VICTORY MECHANICAL SERVICES, INC.

Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure, serve this list of requested documents to accompany the subpoena contemporaneously issued.

On March 9, 2015, the Saint Thomas Entities served their Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action and Requests for Production on Victory Heating & Air Conditioning Co. and Victory Mechanical Services ("Victory"). In order to minimize the impact on Victory created by having to respond to multiple sets of discovery, the Tennessee Clinic Defendants hereby adopt and incorporate the subpoena duces tecum served by the Saint Thomas Entities with slight modifications.

INSTRUCTIONS AND DEFINITIONS

The Tennessee Clinic Defendants adopt and incorporate as if stated fully herein the preamble and "Instructions and Definitions" sections of the Saint Thomas Entities' Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action and Requests for Production on Victory.

NOTICE OF REQUESTED DOCUMENTS

In order to minimize the impact of discovery on Victory, these Tennessee Clinic Defendants hereby adopt and incorporate, as if stated fully herein, the following Requests for Production from the Saint Thomas Entities Requests for Production:

RFP 1 RFP 2 RFP 3 RFP 5 RFP 6 RFP 7 RFP 8 RFP 9 RFP 11 RFP 15 RFP 18 RFP 19 RFP 20

RFP 21 RFP 22 RFP 23.

The Tennessee Clinic Defendants also request:

1. Any marketing materials you provided to NECC or Ameridose specifically related to your qualifications to install and maintain HVAC units in certified cleanrooms.

RESPONSE:

2. Any and all documents related to complaints lodged by NECC (or persons on its behalf) to you about the HVAC units in the NECC cleanrooms potentially contributing to environmental contamination.

RESPONSE:

3. Any and all documents Victory has already produced in this litigation to other parties relevant to its relationship with NECC.¹

RESPONSE:

4. Any document that identifies what Victory employees or agents were responsible for the installation and management of the HVAC units in the NECC cleanrooms.

RESPONSE:

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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Attorneys for the Tennessee Clinic Defendants

^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.

¹ If these documents are housed in a repository created for this litigation or other web-based repository, these Defendants simply request access.

CERTIFICATE OF SERVICE

I certify that this document was served on Victory Heating and Air Conditioning Co., Inc. and Victory Mechanical Services, Inc. via email, was filed through the CM/ECF system, will be served electronically to the registered participants identified on the Notice of Electronic Filing, and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 20th day of March, 2015.

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/s/ Chris J. Tardio

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